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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/070,823

07/15/2002

Boris Beyersdorff

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09/23/2004

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EXAMINER

COMSTOCK, DAVID C

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,823

Applicant(s)

BEYERSDORFF ET AL.

Examiner

David Comstock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-118 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-39, 41-43, 45-78, 81-85, 89-92 and 96-118 is/are rejected.
- 7) ☒ Claim(s) 40, 44, 79, 80, 86-88 and 93-95 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/02; 11/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 62, "the pivot element" lacks antecedent basis.

Claims 70-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 70, "the three arms" lacks antecedent basis.

Claim 74, it is unclear what is meant by "the third arm includes a third arm."

Applicant should clarify whether these refer to the same arm or if they refer to separate and distinct arms and provide appropriate antecedent basis for the same.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 29, 30, 32-36, 45, 48, 53-55, 63-66, 68-77, 81, 82, 84, 85 and 96-118, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Morrison (3,486,505; cited by Applicant).

Morrison discloses a surgical device comprising an upper arm or lever 11 and an adjacent lower arm or lever 11,16 that pivot about a mounting structure 17 that separates the arms (see Figs. 1-5). The mounting structure serves as a fulcrum for the arms and includes an effective pivot axis for the arms about its center. The arms each include adjacent retention devices 12. The surgical device includes an elongated pusher/spreader, i.e. the feed rod 15 and the block 14. The distal end of the block functions as a pusher while the top and bottom surfaces of the block 14 function as spreader elements that are effectively mounted on inner planar surface structures of the arms and slidable therealong. The pusher element portion is below the top surface of the spreader element portion. The block can be selectively moved from a location distal of the fulcrum to a location adjacent the distal end of the arms/levers (cf., e.g., Figs. 1 and 2). Any portion of the arms/levers can be grasped and accordingly can be considered a handle. A working space is capable of being defined between planes passing through the extents of the outer surfaces of the retention devices 12 such that the arms and the pusher/spreader element are completely within the working space. The lower arm comprises a rectangular cross-section. The upper arm 11 can nest within or dip below the legs 16 of the lower arm 11 (see hidden lines in Fig. 1). The region between the legs 16 of the lower arm constitutes a receiving chamber and/or a single groove (i.e. channel). A third element is capable of being inserted near the pivot end of the device if the pusher/spreader is fully retracted. The arms have a greater spacing at their pivoted end near the fulcrum or mounting structure 17 than at their

distal free ends. The arms are capable of being spread apart independently of the spreader element, for example, by being pulled apart by hand.

Claims 26, 29, 33, 34, 38, 48, 53, 54, 68-71, 73, 75, 76, 81 and 82, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Gau (FR 2 737 656; cited by Applicant).

Gau discloses a tool 1,2,3 for inserting an intervertebral implant 50,51,52 (see Figs. 1-4). The tool comprises an upper arm 3 pivotally attached to an adjacent lower arm 2. Each arm comprises a pair of parallel legs 23,33 each having respective retention pins 22,32. The legs define a receiving chamber therebetween that is capable of accommodating an implant element that could be guided longitudinally, for example by hand, if desired, within the chamber. The sleeve 1 comprises a longitudinal guide structure for retaining the tool in an expanded condition for inserting the implant including its third portion 50. The guide structure can be considered to be a pusher and pusher rod 4 where the functional language does not demand the capability to drive the implant along the device. Alternatively, the rod 4 can be considered to be the spreader element since it is capable of spreading the device, i.e. retaining the device in a spread configuration. However, Gau cannot be interpreted as disclosing both a pusher and a spreader simultaneously. The arms are capable of having a greater spacing at their pivotally supported ends than at their free ends due to the channel 30 in the upper arm. The upper arm 3 comprises a single rod portion at the pivotally supported end thereof that is located centrally between the two legs 20,23 of the lower arm 2 (see Fig. 1). The arms are pivotable away from each other. When the implants are in their closest

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proximity to each other, the central portion of the upper arm is between the legs 20,23 of the lower arm 2. The device is capable of being positioned in a working configuration wherein planes passing through the outer surfaces of the implant define a working space in which the components of the device operate (e.g. when the upper arm 3 and lower arm 2 are in an expanded or separated condition). The implant includes a lower part 51 an upper part 52 and a third part 50 located between the lower and upper parts. The lower part and third part nest within a cavity of the upper part 52 (see Fig. 4). The lower arm 2 comprises a mounting block extending up from its bottom surface, which may be considered a bottom plate. The upper arm 3 is pivotally connected to the mounting block of the lower arm 2 about the fulcrum or pivot 21.

Claims 59 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertagnoli (5,571,109; cited by Applicant).

Bertagnoli discloses a device 10 comprising an arm structure which includes a pair of parallel legs 11,12 (Fig. 11). The legs have opposed grooves facing each other therealong. The device includes a recess formed by the two side walls, which at the end thereof include end walls (i.e. the end surfaces of the side walls). The device is capable of being used with a third part, for example an implant, having lateral edges which engage the grooves through an open end opposite the end wall and that can be moved along the grooves into a lower part. It is noted that the claim is directed to the instrument and not the implant. Accordingly, Bertagnoli need only satisfy the structural elements pertaining to the instrument and at least be capable of performing the intended use with regard to the implant. There is nothing in Bertagnoli to indicate that it

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could not perform the noted function if one desired to use it for such a purpose. In fact, Bertagnoli discloses using the arm and grooves for guiding various tools and implants (col. 2, lines 17-21).

Claims 89 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller (4,997,432; cited by Applicant).

Keller discloses a device and method for inserting an intervertebral implant comprising assembling upper and lower parts 3 of an implant on the device 9, inserting the device in an intervertebral space, spreading the parts apart, and moving a longitudinal guide 23 along an opening of the device to move a third part 4 into the space between the upper and lower parts (see Figs. 1-3 and 7-9; col. 2, lines 1-7 and 18-27; and col. 3, lines 28-42 and 54-55). The lower part comprises a recess 7 formed by a base 5, three contiguous raised sides each comprising one-third of the circumference of the device, and one open top side (see Fig. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 28, 31, 46, 49-52, 56-62 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (3,486,505; cited by Applicant) in view of Bertagnoli (5,571,109).

Morrison discloses the claimed invention except for the opposed grooves. Bertagnoli discloses a similar device 10 and teaches the desirability of providing opposed longitudinal grooves 15 to provide a keyway to accurately guide implants 60 and ensure a rapid and exact surgical procedure (see, e.g., Figs. 1A, 1B, 3, 6, 9, 11; col. 1, lines 40-46; col. 2, lines 18-31, 45-49; and col. 4, lines 8-9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the surgical device of Morrison with opposed longitudinal grooves, in view of Bertagnoli, in order to accurately guide the implants and ensure a rapid and exact surgical procedure. It would have been further obvious to one having ordinary skill in the art at the time the invention was made to position the grooves at any location on the device, since it has been held that the mere relocation of elements of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Claims 37, 47 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (3,486,505; cited by Applicant).

A rack and pinion drive and a screw-threaded drive are equivalent incremental advancement mechanisms known in the art. Therefore, it would have been obvious to one of ordinary skill in the art to construct the device of Morrison with a rack and pinion drive instead of a screw-threaded, as such would merely constitute substitution of functionally equivalent incremental advancement mechanisms well-known in the art. Furthermore, it would have been an obvious matter of design choice to form the upper bar with a circular cross-section since Applicant has not disclosed that the circular cross-section solves any stated problem or is for any particular purpose and it appears

that the invention would perform equally well without specifically having the circular cross-section. Moreover, a circular cross-section is nothing more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 39, 41-43 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gau (FR 2 737 656; cited by Applicant) in view of Shapiro et al. (6,436,139).

Gau discloses the claimed invention except for the pins comprising a rotation lock. Shapiro et al. disclose an implant and driving tool and the desirability of providing a rotation lock, i.e. a tool having an implant retaining pin with threads that cooperate with the implant, to receive the insertion tool and positively engage the implant while simplifying the insertion of the implant (see Fig. 1; col. 1, lines 49-51; and col. 3, lines 46-52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tool of Gau with a rotational lock, i.e. the threaded pin interface, in view of Shapiro et al., in order to receive the insertion tool and positively engage the implant while simplifying the insertion of the implant.

Allowable Subject Matter

Claims 40, 44, 79, 80, 86-88 and 93-95 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.



D. Comstock
19 September 2004



EDUARDO C. ROBERT
PRIMARY EXAMINER